Medacta International

510(k) Summary

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Date Prepared: November 22, 2013

DEVICE INFORMATION

Trade/Proprietary Name: GMK Short Stem
Common Name: Total Knee Prosthesis
Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
21 CFR 888.3560
Class II
Device Product Codes: JWH

Predicate Devices:

510(k)	Product	510(k) Holder	Clearance Date
K090988	GMK Total Knee System	Medacta International	7/10/2009
K121416	GMK Sphere	Medacta International	7/30/2012
K043101	NexGen	Zimmer	3/7/2005

Product Description

The GMK Short Stem is a tibial extension stem made of titanium alloy (Ti6-Al4-V) according to ISO5832-3:1996, Implants for Surgery – Metallic materials – Part 3: Wrought titanium 6-aluminum 4-vanadium alloy. The GMK Short Stem has a diameter of 11mm and a length of 30mm. The GMK Short Stem is compatible with the tibial baseplates of the GMK Total Knee System (K090988) and the tibial baseplates of the GMK Sphere Total Knee System (K121416).

Indications for Use

The GMK knee prosthesis is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.

This knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
- Avascular necrosis of femoral condyle.
- Post traumatic loss of joint configuration.
- Primary implantation failure.

Tibial augments are to be attached to the tibial baseplate with both the fixing cylinders and bone cement.

In case a semi-constrained liner is used, an extension stem must be implanted both on the tibial and on the femoral components.

Comparison to Predicate Devices

The indications for use, design features and materials of the GMK Short Stem are substantially equivalent to those of the predicate devices. The GMK Short Stem has the same materials, diameter, and morse taper as the GMK 65mm tibial extension stem cleared under K090988 and has a similar length as the tibial extension stem cleared under the Zimmer NexGen predicate device. The safety and effectiveness of the GMK Short Stem are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Performance Testing

A review of the mechanical data indicates that the GMK Short Stem is equivalent to devices currently cleared for use and is capable of withstanding expected in vivo loading without failure. The GMK Short Stem has the same specifications (materials, diameter, and morse taper) as the 65mm GMK tibial extension stem cleared under K090988. Since the modular connection to the GMK tibial baseplate (K090988) is the same, the test performed on the tibial modular connection (K090988) is also applicable to the connection when the GMK Short Stem is used and no further tests are needed to prove substantial equivalence.

The modification to the device system to include the addition of the GMK Short Stem was evaluated by risk analysis to identify any new risks associated with the change. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the standards, FDA guidance, and comparison to the predicate device system. The GMK Short Stem was compared to the worst case K090988 GMK Total Knee component in terms of modular connection to the tibial baseplate and it was determined that the GMK Short Stem is not worst case.

Conclusion:
Based on the above information, the GMK Short Stem can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

Medacta International SA
% Mr. Adam Gross
Director of Regulatory, Quality and Compliance
4725 Calle Quetzal, Unit B
Camarillo, California 93012

Re: K133630
Trade/Device Name: GMK Short Stem
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: November 22, 2013
Received: November 26, 2013

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133630

Device Name: GMK Short Stem

Indications for Use:

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- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
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Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices